IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2738
This Document Relates To All Cases	

DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS OF DEFENDANTS' MOLECULAR BIOLOGISTS DRS. NEEL, SHIH, BOYD AND BIRRER

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Drs. Benjamin Neel, Ie-Ming Shih, Jeff Boyd and Michael Birrer comprise a veritable Who's Who of leading cancer researchers. As Director of NYU's Perlmutter Cancer Center, Dr. Neel is responsible for all cancer research at NYU Langone Health and has undertaken significant research on ovarian cancer pathogenesis and functional genomics. Along with another defense expert (Dr. Robert Kurman), Dr. Shih, a Distinguished Professor of Gynecologic Pathology at Johns Hopkins, revolutionized the field in determining that high grade serous ovarian cancers ("HGSOC") likely begin in the fallopian tubes rather than the ovaries. Dr. Boyd is the founding director of the Center for Genomic Medicine at the Miami Cancer Institute and focuses his research on the genetics and molecular genetics of gynecologic and breast cancers. And Dr. Birrer is an internationally recognized expert in gynecologic oncology who has hundreds of publications and whose research has focused almost entirely on the molecular genetics of ovarian cancer. This all-star team of experts evaluated plaintiffs' experts' biological plausibility hypotheses and unanimously concluded that these hypotheses lack scientific support and that plaintiffs' experts' methods are unreliable.

Plaintiffs' motion essentially ignores the core of these experts' opinions, which set forth their critiques of ***plaintiffs' experts' own methodologies***, including Drs. Neel and Boyd's critiques of Dr. Saed's flawed experiments and Drs. Birrer and Shih's critiques of plaintiffs' experts' migration and inflammation opinions.

And the arguments that plaintiffs do make are entirely without merit. ***First***, plaintiffs' principal basis for seeking to exclude these experts' opinions is that they purportedly ignored plaintiffs' novel and unsupported allegations that talc contains asbestos and heavy metals – and that it is biologically plausible for these substances to cause ovarian cancer. This contention lacks merit. For one thing, these experts critique opinions by ***plaintiffs' experts*** that focus on cosmetic talcum powder, not asbestos, heavy metals and fibrous talc. In addition, the relevant scientific articles (including the studies cited by plaintiffs' experts) involved commercial talc, which plaintiffs' experts contend is ***always*** intermixed with asbestos, heavy metals and fibrous talc. Thus, any purported ill effects of those alleged contaminants would have been captured in the studies on which defendants' experts' opinions are based. Accordingly, for these reasons, too, plaintiffs' complaints that Drs. Shih, Neel, Birrer and Boyd did not consider the contents of the Products are unavailing.

Second, plaintiffs also offer a smattering of other arguments challenging certain limited portions of defendants' experts' reports, but those arguments fundamentally misperceive the nature of the experts' opinions, understate their relevant qualifications and misread the relevant deposition testimony or the relevant law. Specifically, plaintiffs' argument that Drs. Shih and Neel are unqualified to address the epidemiological literature is patently meritless,

particularly given that plaintiffs' pathology expert discussed epidemiology for pages in her report (which barely touched on pathology).[1] Plaintiffs also lodge reliability objections to Drs. Neel and Shih's biological plausibility opinions (which plaintiffs oddly characterize as epidemiology opinions), but those challenges likewise distort the experts' actual opinions and testimony and should similarly be rejected.

Third, plaintiffs challenge Dr. Boyd's qualifications to briefly mention that he agrees with the International Agency of Research on Cancer's conclusion regarding "migration" – i.e., that the evidence that talc can reach the ovaries after perineal dusting is weak. To call this an opinion is far-fetched. In fact, Dr. Boyd addresses migration merely to provide the background for an opinion that plaintiffs do not move to exclude: that Dr. Saed's *in vitro* experiment cannot be reliably extrapolated to humans because it used a dose well in excess of the amount that could actually reach living ovarian tissue. In any event, as a prominent ovarian

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[1] Plaintiffs also challenge Dr. Boyd's qualifications to opine on epidemiology. Although this argument is similarly meritless, it is also moot because Dr. Boyd made clear at his deposition that he is not offering epidemiology opinions. (Dep. of Jeff Boyd, Ph.D. ("Boyd Dep.") 69:11-14, Apr. 8, 2019 (attached as Ex. C to Pls.' Steering Committee's Mem. of Law in Supp. of its Mot. to Exclude the Expert Ops. of Defs.' Molecular Biologists Drs. Neel, Shih, Boyd, and Birrer ("Pls.' Br."), May 7, 2019 (ECF No. 9743-1)) (Dr. Boyd testifying that he would "not voluntarily be offering any opinions" on epidemiology, but that he would "do [his] best to answer any question" asked).)

cancer researcher, Dr. Boyd is clearly qualified to address IARC's statement on migration, and plaintiffs' argument fails for this reason as well.

Fourth, plaintiffs seek to exclude Dr. Shih's histopathological study showing no inflammation associated with ovarian cancer precursor lesions. According to plaintiffs, the study should be excluded because it is ongoing, it lacks a written methodology, and Dr. Shih did not take contemporaneous notes when he examined the slides. These arguments are based on mischaracterizations of both Dr. Shih's study and his deposition testimony. In fact, Dr. Shih's study is not incomplete and does spell out his methodology. Moreover, it would have made no sense for Dr. Shih to take notes because he recorded his observations and provided photographs of the slides themselves so that any of plaintiffs' experts could replicate his work if they so chose.

For all of these reasons, as elaborated in greater detail below, the Court should deny plaintiffs' motion to exclude the opinions of Drs. Neel, Shih, Boyd and Birrer.

BACKGROUND

Plaintiffs have challenged the cancer biology opinions of Drs. Benjamin Neel, Ie-Ming Shih, Jeff Boyd and Michael Birrer.

A. Benjamin G. Neel, MD, Ph.D.

Dr. Neel is the Laura and Isaac Perlmutter Director and Professor of Medicine at New York University ("NYU") School of Medicine.[2] In that role, he is responsible for all cancer research at NYU Langone Health.[3] Dr. Neel also runs his own research laboratory that focuses on cancer cell signaling, and he is widely recognized as an expert in that field.[4] A primary focus of Dr. Neel's research has been the biology of breast and ovarian cancer. He has conducted significant work in the area of ovarian cancer pathogenesis, including cellular signaling and the role of certain pathway mutations in the development of disease and malignancy, and he has authored numerous papers on the subject of ovarian cancer.[5] He has published 234 peer-reviewed primary manuscripts and 33 invited reviews, and has been cited more than 45,000 times.[6] Dr. Neel was the first winner of the Gertrude Elion Award of the American Association for Cancer Research, named for Dr. Gertrude B. Elion, who was awarded the Nobel Prize for Medicine in 1988.

Based on his expertise in cancer biology, medicine, signal transduction and ovarian cancer pathobiology, Dr. Neel opines that "[t]alc is not genotoxic, does not

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2 (Neel Rep. at 2.)

3 (*Id.*)

4 (*Id.*)

5 (*Id.* at 2-3.)

6 (*Id.* at 3.)

cause mutations, does not cause inflammation in the female genitourinary tract and has not been shown to cause ovarian cancer."[7] Dr. Neel also reviewed Dr. Saed's expert report and the experiment it described and concluded that his "work is rife with errors and overstated claims that betray a lack of understanding of cancer genetics."[8]

B. Ie-Ming Shih, MD, Ph.D.

Dr. Shih is a board-certified gynecologic pathologist at Johns Hopkins who specializes in the carcinogenesis and etiology of ovarian cancer (i.e., how ovarian cancer develops).[9] Dr. Shih has conducted significant research in the areas of carcinogenesis, genomic landscapes and the pathogenesis of ovarian cancer.[10] He has published more than 350 original articles in prestigious medical journals, which have been cited more than 32,000 times, making him one of the most cited gynecologic pathologists in the world.[11]

Dr. Shih reviewed the opinions of two plaintiffs' experts: Dr. Ghassan Saed, an associate professor at Wayne State University who has only rarely secured NIH-

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7 (*Id.* at 14 (emphasis omitted).)

8 (*Id.* at 28.)

9 (*See* Expert Report of Ie-Ming Shih, M.D., Ph.D. ("Shih Rep.") at 1-2, Feb. 25, 2019 (attached as Ex. C20 to Omnibus Certification of Julie L. Tersigni ("Tersigni Cert."), May 7, 2019 (ECF No. 9723-2)).)

10 (*Id.* at 2.)

11 (*Id.*)

level funding and whose papers are generally published in much lower-ranking journals,[12] and Dr. Sarah Kane, a private-practice pathologist in Massachusetts who, according to her CV, has not published anything in seven years.[13] Dr. Shih was asked to "assess [the] scientific validity" of Dr. Saed's and Dr. Kane's work "and the reliability of the methods [they] employed."[14]

Following that review, Dr. Shih offered four opinions. First, he opines that Drs. Saed and Kane's opinions on biological plausibility are not the product of

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[12] (*See, e.g.*, Expert Report of Dr. Ghassan M. Saed ("Saed Rep."), Ex. A (Dr. Saed's curriculum vitae), Nov. 16, 2018 (attached as Ex. C17 to Tersigni Cert.); Dep. of Ghassan Saed, Vol. 1 279:11-17, Jan. 23, 2019 (attached as Ex. B12 to Tersigni Cert.) (admitting he is not a full professor because "[a]pplying for a full professor . . . requires current NIH NCI only funding"); Expert Report of Brooke Taylor Mossman, M.S., Ph.D. at 26-27, Feb. 25, 2019 (attached as Ex. C11 to Tersigni Cert.) (evaluating Dr. Saed's CV and noting, among other things, that his only membership in a scholarly journal is as an editor of *Gynecology and Obstetrics Research-Open Journal*, which is not indexed in PubMed and does not report an index factor).) Notably, the publisher of *Gynecology and Obstetrics Research-Open Journal*, Openventio, has been repeatedly identified as a predatory pay-to-publish operation. *Beall's List of Predatory Journals and Publishers*, https://beallslist.weebly.com/ (last updated May 20, 2019) (attached as Ex. J5 to the Suppl. Certification of Julie L. Tersigni ("Suppl. Tersigni Cert.")); *see also* Chawla, *The Undercover Academic Keeping Tabs On 'Predatory' Publishing*, Nature, Mar. 16, 2018, https://www.nature.com/articles/d41586-018-02921-2 (attached as Ex. A161 to Suppl. Tersigni Cert.) (describing the history of Beall's List of predatory publishers).

[13] (*See* Expert Report of Sarah E. Kane, M.D., Ex. A, Nov. 15, 2018 (attached as Ex. C38 to Tersigni Cert.).)

[14] (Shih Rep. at 1.)

reliable methodologies and are contrary to established scientific knowledge.[15] Second, he opines that Dr. Saed's experimental results are the product of a flawed research design.[16] Third, he opines, based on an extensive literature review and his own original research, that he did not find any evidence – whether molecular, biological, pathological, epidemiological or otherwise – that supports the conclusion that talc can cause ovarian cancer.[17] And fourth, he opines that Dr. Saed failed to adequately disclose significant conflicts of interest in his manuscript.[18]

To supplement his exhaustive literature review and inform his opinions, Dr. Shih performed his own original study (at his own initiative) to determine whether inflammation plays a role in the development of ovarian cancer. For that study, Dr. Shih selected 59 tissue samples. These samples included serous precancerous lesions of two types – serous tubal intraepithelial carcinoma ("STIC") and p53 signature[19] – both with and without concurrent ovarian cancer. He also selected

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15 (*Id.*)

16 (*Id.*)

17 (*Id.* at 1, 9-15.)

18 (*Id.* at 1.)

19 STIC is a precursor lesion to HGSOC that is found in the fallopian tubes. "Discovery of STIC lesions in *BRCA 1/2*-mutant patients undergoing prophylactic removal of their fallopian tubes and ovaries . . . led to the [fallopian tube] 'cell-of-origin' concept" of HGSOC. (Expert Report of Benjamin Neel, M.D., Ph.D.

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samples of normal fallopian tissue to serve as negative controls and carcinomas to serve as positive controls.[20] He then examined each sample under a microscope for specific signs of chronic inflammation, using a well-established diagnostic method that he has used in both his clinical and peer-reviewed academic work.[21] Dr. Shih detected signs of chronic inflammation in all of the cases of ovarian carcinoma, but in none of the precancerous lesions, or in the samples of healthy tissue.[22] These observations provide further evidence that the inflammation associated with ovarian cancer arises in full-blown carcinomas ***after their development*** rather than in cancer precursors, "refuting the hypothesis that chronic inflammation is the cause of ovarian cancer."[23]

C. Jeff Boyd, Ph.D.

Dr. Boyd is a tenured professor and the chair of the Department of Human and Molecular Genetics and professor of Obstetrics and Gynecology, as well as associate dean for Basic Research and Graduate Programs at the Herbert Wertheim

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("Neel Rep.") at 11, Feb. 25, 2019 (attached as Ex. C10 to Tersigni Cert.).) The p53 signature is a lesion indicative of mutations of TP53, a tumor suppressor gene. Mutations of TP53 are present in almost all HGSOCs. (Shih Rep. at 11.)

20 (*See* Shih Rep. at 15, 25-26.)

21 (*See id.* at 26-27.)

22 (*See id.* at 26, 29.)

23 (*See id.* at 27-28.)

College of Medicine at Florida International University.[24] He also serves as the associate deputy director of Translational Research and Genomic Medicine at the Miami Cancer Institute of Baptist Health South Florida.[25] He is the founding director of the Center for Genomic Medicine at the Miami Cancer Institute.[26] Dr. Boyd's research focuses on the genetics and molecular genetics of gynecologic and breast cancers.[27]

Dr. Boyd's report primarily addresses Dr. Saed's experiment and opinions. As Dr. Boyd explains, Dr. Saed used highly flawed research methods and misinterpreted his results. Dr. Boyd also expressed concerns regarding Dr. Saed's handling of his laboratory notebook and apparent manipulation of data. Dr. Boyd explains why, even if Dr. Saed's work had been conducted in a reliable manner, it would not show, or even suggest, that talc can induce carcinogenesis or neoplastic change *in vitro*, much less in the human body.[28]

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24 (Expert Report of Jeff Boyd, Ph.D. ("Boyd Rep.") at 1, Feb. 25, 2019 (attached as Ex. C22 to Tersigni Cert.).)

25 (*Id.*)

26 (*Id.*)

27 (*Id.*)

28 (*E.g.*, *id.* at 19.)

D. Michael Birrer, MD, Ph.D.

Dr. Birrer is a leading medical oncologist and a Member of the Experimental Therapeutics Program of the O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham Comprehensive Cancer Center.[29] He is internationally recognized as an expert in gynecologic oncology and has published more than 380 peer-reviewed manuscripts, book chapters and review articles.[30] He is also the Chair and Chair Emeritus of the Department of Defense Ovarian Cancer Research Program.[31] Dr. Birrer's research efforts have focused almost entirely on the molecular genetics of ovarian cancer.[32]

Dr. Birrer was asked to address the biological plausibility of plaintiffs' theory that the use of cosmetic talc can cause ovarian cancer.[33] Dr. Birrer explains in his report that talc is not generally accepted as a cause of ovarian cancer.[34] He further opines that the studies plaintiffs' experts cite fail to support – and if

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29 (Expert Report of Michael Birrer, M.D., Ph.D. ("Birrer Rep.") at 1, Feb. 25, 2019 (attached as Ex. C33 to Tersigni Cert.).)

30 (*Id.*)

31 (*Id.*)

32 (*Id.* at 2.)

33 (*Id.*)

34 (*Id.* at 26.)

anything disprove – a causal relationship between talc and ovarian cancer.[35] Dr. Birrer has also opined that Dr. Saed's experiments are "deeply flawed."[36]

ARGUMENT

I. DEFENDANTS' EXPERTS DID NOT NEED TO CONSIDER PLAINTIFFS' ALLEGATIONS REGARDING ASBESTOS AND HEAVY METALS FOR THEIR OPINIONS TO BE RELIABLE.

Rather than attack the core of these four experts' opinions, plaintiffs argue that their opinions are unreliable because they purportedly did not consider the alleged presence of asbestos and heavy metals in talc in reaching their opinions.[37] This argument makes no sense. The core of these experts' reports are critiques of the ***methodologies*** employed by plaintiffs' biological plausibility experts, and those opinions are unaffected by plaintiffs' allegations regarding heavy metals and asbestos. As noted briefly above:

- Dr. Neel's report addresses existing knowledge about cancer, including that cancer is a genetic disease that disrupts normal cellular regulation, and that cancers (including ovarian cancers) are really a range of diseases with different tissues of origin and mechanisms of carcinogenesis.[38] While Dr. Neel does proffer his own opinions regarding the posited relationship between perineal talc use and ovarian cancer,[39] he focuses much of this discussion on the hypotheses

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35 (*Id.*)

36 (*Id.*)

37 (Pls.' Br. at 10-28.)

38 (Neel Rep. at 2-14.)

39 (*E.g.*, *id.* at 14-17.)

and methods of plaintiffs' experts. For example, Dr. Neel opines that Dr. Saed's work is "technically and conceptually flawed," "rife with errors and overstated claims" and betrays a lack of understanding of cancer genetics.[40] He also opines that the interpretations that Dr. Zelikoff and other plaintiffs' experts offer of various published articles (and the experiments reported in those articles) are flawed and do not support their biological plausibility conclusions.[41] These opinions in no way depend on what constituents plaintiffs' experts contend may be present in the Products.

- Dr. Shih's report begins with a critique of the methods employed and claims made by Drs. Saed and Kane.[42] Dr. Shih's discussion of Dr. Saed's report and paper addresses study design and interpretation issues, such as talc concentration, choice of cell lines, interpretation of CA-125 findings, extrapolating from in vitro experiments and claims regarding SNP mutations and cell proliferation.[43] Dr. Shih also discusses significant flaws in Dr. Kane's opinions regarding lymphatic transport and the alleged similarities between asbestos and talc.[44] As Dr. Shih concludes, "Dr. Saed's and Dr. Kane's opinions related to the biological plausibility of the theory that talc powder use can cause ovarian cancer or increase the risk of ovarian cancer are not the product of reliable methods and are contrary to established scientific knowledge."[45] None of these opinions depends on what constituent minerals or fragrances are alleged to be present in the Products. Dr. Shih also includes a section in his report on the posited causal relationship between talc and ovarian cancer, and much of this section relates to basic cancer biology, what is known about the causes and origins of ovarian cancer, and how much of the epidemiology regarding perineal use of talc fails to differentiate

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40 (*Id.* at 17, 28.)

41 (*See id.* at 23-25.)

42 (Shih Rep. at 4-9.)

43 (*Id.* at 4-8.)

44 (*Id.* at 8-9.)

45 (*Id.* at 1.)

among the subtypes of ovarian cancer – opinions that again do not depend on what plaintiffs' experts allege may be found in the Products.[46] Dr. Shih next explains the problems with Dr. Saed's failure to disclose important conflicts of interest.[47] And finally, Dr. Shih attaches a description of a study he performed in forming his opinions, the reasoning for which is not specific to talc and thus likewise does not depend on what plaintiffs' experts contend is always present in talc.[48]

- Dr. Boyd dedicates virtually his entire report to critiquing the work of Dr. Saed. In particular, he focuses on the methods Dr. Saed employed in his study – i.e., his choice of solvent for dissolving talc, his determination of talc dosage, and his selection of controls and cell lines.[49] Dr. Boyd's critique also addresses Dr. Saed's interpretation of his results – i.e., his findings regarding serum CA-125 levels and cell proliferation and apoptosis.[50] Dr. Boyd notes serious limitations in Dr. Saed's study that preclude the conclusions Dr. Saed sought to draw, including the impossibility of Dr. Saed's theory that brief exposure to talc caused SNP mutations in the treated cells, and the inherent limitations in drawing conclusions from in vitro studies.[51] Dr. Boyd concludes that Dr. Saed's work is full of "methodological flaws," that he "layers speculation upon speculation," [52] and that even if his research had been reliably performed, "[t]he gap between his research . . . and elucidating the origins of ovarian cancer" would still be too large to support the biological plausibility of plaintiffs' theories.[53] Again, none of these opinions depends in any way on what

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46 (*Id.* at 9-11, 13-14.)

47 (*See id.* at 16-17.)

48 (*See id.* at 24-29.)

49 (Boyd Rep. at 4-8.)

50 (*Id.* at 8-11.)

51 (*Id.* at 11-19.)

52 (*Id.* at 4.)

53 (*Id.*)

constituent minerals or fragrances are alleged to be present in the Products.

- The core of Dr. Birrer's report is a critique of plaintiffs' experts' methodologies with respect to biological plausibility.[54] As part of his critiques, Dr. Birrer surveyed and discusses the relevant scientific literature. Dr. Birrer also dedicates an entire section of his report to the methodological problems pervading Dr. Saed's experiments and why they "do not support" plaintiffs' experts' biological plausibility conclusions.[55] He further opines that Dr. Saed's experiments "are deeply flawed at many levels," and that these flaws render his report "at times uninterpretable and certainly unreliable."[56] These critiques in no way depend on what constituent minerals or fragrances are alleged to be present in the Products.

In short, the alleged contamination of talc with other substances is utterly irrelevant to virtually all of the cancer biologists' opinions.

This is also true to the extent defendants' experts offered affirmative opinions regarding biological plausibility. After all, defendants' experts' opinions were based on a series of *in vitro* and animal studies that sought to investigate the carcinogenicity of talcum powder. Among other things, these studies injected talc into rats, exposed rats to talc perineally and tested cells that were treated with talc.[57] Notably, these are many of the same studies relied on by plaintiffs' experts

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54 (Birrer Rep. at 4-17.)

55 (*Id.* at 3; *see also id.* at 19-26 (detailing the methodological problems with Dr. Saed's experiments).)

56 (*Id.* at 26; *id.* at 19.)

57 *See, e.g.*, Fletcher, et al., *Molecular Basis Supporting the Association of Talcum Powder Use with Increased Risk of Ovarian Cancer*, Reprod Sci. (2019)

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as well. And plaintiffs' experts never suggest that the studies are irrelevant because the talc there somehow had different components or contaminants than the talc in the Products. In any event, plaintiffs' experts contend that there is no such thing as asbestos-free talc,[58] which means that under their theories, the talc used in

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(attached as Ex. A39 to Tersigni Cert.) (using Johnson's Baby Powder) (the draft version of which is cited in Birrer Rep. at 24-26; Boyd Rep. at 10-11; Neel Rep. at 22-23; Shih Rep. at 6-8, 16-17); Shukla, et al., *Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity*, 41 Am J Respir Cell Mol Biol. 114 (2009) (attached as Ex. A131 to Tersigni Cert.) (testing the effect of, inter alia, talc with some impurities on gene expression of cells *in vitro*) (cited in Birrer Rep. at 16; Neel Rep. at 21); Keskin, et al., *Does Long-Term Talc Exposure Have a Carcinogenic Effect on the Female Genital System of Rats? An Experimental Pilot Study*, 280 Archives Gynecol Obstet. 925 (2008) (attached as Ex. A85 to Tersigni Cert.) (finding no neoplastic transformation in rat ovaries after intravaginal or perineal talc application) (cited in Boyd Rep. at 17-18; Neel Rep. at 21; Shih Rep. at 14, 15 n.2); Buz'Zard & Lau, *Pycnogenol® Reduces Talc-Induced Neoplastic Transformation in Human Ovarian Cell Culture*, 21 Phytotherapy Res. 579, 580 (2007) (attached as Ex. A16 to Tersigni Cert.) (testing the possibility of neoplastic transformation among cells *in vitro* after treatment with "[t]alc . . . purchased from Sigma") (cited in Birrer Rep. at 14-15; Neel Rep. at 25-26); Hamilton et al., *Effects of Talc on the Rat Ovary*, 65 Br J Exp Pathol. 101, 102 (1984) (attached as Ex. A53 to Tersigni Cert.) (finding no neoplastic transformation in rat ovaries after injection of "Italian 00000" talc) (cited in Birrer Rep. at 14, 16-17; Boyd Rep. at 17; Neel Rep. at 21).

[58] (*See, e.g.*, Expert Report of Anne McTiernan, M.D., Ph.D. at 56, Nov. 16, 2018 (attached as Ex. C7 to Tersigni Cert.) ("It is important to note that talc is not asbestos-free. Talcum powder products contain other, potentially carcinogenic substances; of greatest concern is the presence of asbestos in talc, and the presence of talc with asbestiform fibers (fibrous talc), in these products."); Expert Report of Arch Carson, M.D., Ph.D. at 4, Nov. 16, 2018 (attached as Ex. C9 to Tersigni Cert.) ("Talc deposits are often intermingled with asbestos and vice versa."); Expert Report of Daniel L. Clark-Pearson, M.D. at 6, Nov. 16, 2018 (attached as Ex. C14

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the relevant studies would presumably have contained the same accessory minerals allegedly present in the Products. In short, plaintiffs apparently are taking the position that defendants' experts should not have relied on talc studies –even though this litigation is about talc, even though their experts relied on talc studies, and even though, if their theories were right, any talc used in scientific studies would have been contaminated with asbestos and heavy metals to the same extent as defendants' Products. This argument is frivolous.

For all of these reasons, plaintiffs' arguments should be rejected.[59]

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to Tersigni Cert.) ("Talcum powder also contains other carcinogens including asbestos, talc containing asbestiform fibers (fibrous talc), heavy metals such as nickel, chromium and cobalt (possible 2b), and other inflammatory agents, toxins, and carcinogens contained in the fragrance chemicals in talcum powder."); Expert Report of Ellen Blair Smith, M.D. at 18, Nov. 16, 2018 (attached as Ex. C16 to Tersigni Cert.) ("There is evidence from medical literature that talcum powders are not pure talc, but contain impurities including asbestos."); Expert Report of Judith Zelikoff, Ph.D. at 8, Nov. 16, 2018 (attached as Ex. C24 to Tersigni Cert.) ("Defendants have claimed that asbestos has been 'eliminated' from cosmetic talc products. However, there is substantial evidence that talcum powder products still contain asbestos.") (footnote omitted); Expert Report of Mark Krekeler, Ph.D. at 5, Nov. 16, 2018 (attached as Ex. C31 to Tersigni Cert.) ("Asbestos minerals . . . are common in talc ores."); Expert Report of Patricia G. Moorman, M.S.P.H., Ph.D. at 34, Nov. 16, 2018 (attached as Ex. C35 to Tersigni Cert.) ("There is also evidence in the medical literature that talc products contain additional constituents that are known ovarian carcinogens, particularly asbestos.").)

[59] As part of this argument, plaintiffs also accuse Dr. Shih of being evasive in answering questions. (Pls.' Br. at 16-19.) These accusations are improper. Plaintiffs are well aware that English is not Dr. Shih's first language, and even the portions of Dr. Shih's deposition transcript that plaintiffs cite make clear that Dr.

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II. DRS. NEEL AND SHIH'S REFERENCES TO EPIDEMIOLOGY ARE WELL WITHIN THEIR QUALIFICATIONS, AND THEIR OPINIONS ARE RELIABLE.

Plaintiffs also seek to bar Drs. Neel, Shih and Boyd – all distinguished experts in gynecological cancer – from offering opinions on epidemiology. As an initial matter, Dr. Boyd could not have been clearer at his deposition that he is ***not*** offering any opinions on epidemiology.[60] Thus, this part of plaintiffs' argument is moot. As to Drs. Neel and Shih, these experts are well qualified to discuss epidemiology – and certainly more so than plaintiffs' expert Dr. Kane, who

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Shih was simply asking for clarity regarding the phrasing of plaintiffs' counsel's questions. (*See id.*)

[60] (Boyd Dep. 69:11-14.) Dr. Boyd's report does not include the word "epidemiology" or any of its variants except in a citation to a journal. (Boyd Rep. at 18-19 n.82.) Nevertheless, plaintiffs attack Dr. Boyd's statement at his deposition that "epidemiological studies are incapable of showing causation," as a purported epidemiologic opinion. (Pls.' Br. at 41.) Even if this could be categorized as an epidemiologic opinion (and it is not), the statement is both correct and well within Dr. Boyd's expertise to offer. It is universally accepted in the scientific community that epidemiology begins, but cannot by itself finish, the causation inquiry. As the Reference Manual succinctly puts it: "epidemiology cannot prove causation." Green et al., Fed. Judicial Ctr., *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 549, 598 (3d ed. 2011) (attached as Ex. A51 to Tersigni Cert.); *see also id.* at 552-53 ("An association identified in an epidemiological study may or may not be causal."). To the extent there are exceptions to this general rule, they certainly do not apply in this context, where the epidemiology suggests, at most, a weak and inconsistent association between exposure and disease. *See id.* at 602 (explaining that "epidemiologist[s] will scrutinize [weak] associations more closely").

provides extensive epidemiology opinions. Nor are plaintiffs able to offer any credible argument that these experts' methodologies were improper.

A. Drs. Neel And Shih Are More Than Qualified To Opine On Epidemiology.

Drs. Neel and Shih offer limited opinions on the epidemiological literature concerning perineal talc use and ovarian cancer[61] and are well within their expertise in doing so. The law is well settled that medical doctors and research scientists such as Drs. Neel and Shih are categorically qualified to offer epidemiological opinions. As courts in this Circuit have recognized, "extensive ***medical training and experience [is a] sufficient" basis "to interpret epidemiological literature***," whether or not the expert is a professional epidemiologist. *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 659 (E.D. Pa. 2012) (emphases added); *see also, e.g., In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, No. 2007-MD-1871, 2011 WL 13576, at *10 (E.D. Pa. Jan. 4, 2011) (expert could "draw conclusions from epidemiological research" although he was "not an epidemiologist" "given [his] credentials as a researcher and published author, as well as clinician"); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 426 (S.D.N.Y. 2016) ("[M]edical doctors do not need to be epidemiologists in order to testify regarding epidemiological studies.").

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[61] (Neel Rep. at 14-16, 27-28; Shih Rep. at 11-13.)

Plaintiffs agree with this principle when it comes to their own experts, but not when it comes to defendants' experts. Indeed, plaintiffs' counsel expressly pressed Dr. Robert Kurman to agree with them at his deposition that pathologists have "a working knowledge of epidemiology" and know perfectly well how to read and interpret epidemiological studies.[62] Needless to say, there is no double standard in the law when it comes to qualifications. Thus, it cannot be seriously contested that two of the world's leading cancer researchers – Drs. Shih and Neel – are more than qualified to interpret epidemiologic literature. *See Cooper v. Meritor, Inc.*, No. 4:16-CV-52-DMB-JMV, 2019 WL 545271, at *4 (N.D. Miss. Feb. 11, 2019).

Plaintiffs nonetheless argue that Drs. Neel and Shih somehow disqualified themselves by testifying at their depositions that they are not "epidemiology experts." This argument is based (like many of plaintiffs' other arguments) on plucking snippets of testimony out of context.

Dr. Neel never suggested that he saw himself as unqualified to interpret epidemiological studies, as plaintiffs contend;[63] to the contrary, he insisted that he was qualified to read, understand, and draw conclusions from epidemiological

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62 (Dep. of Robert Kurman, M.D. 215:8-9, 215:23-24, Apr. 2, 2019 (attached as Ex. B44 to Tersigni Cert.).)

63 (Pls.' Br. at 29-30.)

evidence. In quoting Dr. Neel's statement that he is not an epidemiologist,[64] plaintiffs conspicuously omit that immediately thereafter, Dr. Neel explained that although he is not "an epidemiologist, per se," he "read the epidemiological literature from the standpoint of someone who is trained as a physician and also who is in charge of running the epidemiology and cancer control program for [their] cancer center grant" and that he has "the ability to read" and understand epidemiological studies.[65] Enough said.

Plaintiffs similarly misrepresent the testimony of Dr. Shih, who also made clear at his deposition that he was capable of evaluating epidemiological literature. Plaintiffs highlight Dr. Shih's acknowledgement that he is not "***an epidemiology expert***" specifically.[66] But Dr. Shih also explained in a portion of his deposition that plaintiffs omit from their brief, that "[a]s a scientist, [he] always review[s] epidemiology literature. It's part of [his] background to study it."[67] Nor does the fact that Dr. Shih asked for a copy of the Bradford Hill publication prior to answering questions about the Bradford Hill factors[68] somehow negate his

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64 (*Id.* (quoting Dep. of Benjamin Neel, M.D., Ph.D. ("Neel Dep.") 104:5-14, Mar. 19, 2019 (attached as B6 to Tersigni Cert.)).)

65 (Neel Dep. 104:15-105:4).

66 (Pls.' Br. at 34-35 (quoting Shih Dep. 67:10-68:1).)

67 (Shih Dep. 52:23-53:1; *see* Pls.' Br. at 36-37.)

68 (*See* Pls.' Br. at 35-36 (making this argument).)

qualifications. A deposition is not a memory test, as plaintiffs' counsel themselves assured Dr. Shih at the start of his deposition,[69] and over the course of Dr. Shih's deposition, it became clear that he was more than familiar with the Bradford Hill framework.[70] Finally, plaintiffs' suggestion that Dr. Shih's opinions were largely premised on epidemiology is also misleading.[71] As Dr. Shih, explained, his "opinion is based on [his] literature search about epidemiology, ***chronic inflammation, carcinogenesis, molecular genetics, and [his] 20 years of experience as a scientist and pathologist***."[72]

For all of these reasons, plaintiffs' qualifications arguments should be rejected.

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69 (*See, e.g.*, Shih Dep. 11:7-9 (assuring Dr. Shih, at the beginning of the deposition, that "[t]oday is not going to be a memory test," and that if he "need[ed] to review documents, it's open book").)

70 (*See id.* 255:23-256:7.)

71 (Pls.' Br. at 34 (quoting Shih Dep. 112:9-11).)

72 (Shih Dep. 122:9-14 (emphasis added).)

B. Plaintiffs' Apparent Reliability Challenges To The Biological Plausibility Opinions Offered By Drs. Neel And Shih (Which Plaintiffs Oddly Characterize As Epidemiology Opinions) Also Lack Merit.

Plaintiffs also appear to argue that Drs. Neel and Shih's biological plausibility opinions are in fact unreliable epidemiology opinions.[73] These arguments lack merit, regardless of how the opinions are characterized.

First, plaintiffs assert that Dr. Neel placed too much weight on the biological plausibility factor by suggesting that biological plausibility is "essential" to a showing of causation and that this opinion is contrary to Hill's methodological approach and the opinions expressed in Dr. Merlo's report.[74] But it is entirely reasonable for defense experts to proceed on the understanding that plaintiffs' experts need to identify a biological mechanism that is "substantiated by scientific evidence," *Soldo v. Sandoz Pharm. Corp.*, No. 98-1712, 2003 WL 22005007, at *4 (W.D. Pa. Jan. 1, 2003), rather than "an unproven hypothesis," *In re Accutane Prods. Liab. Litig.*, 511 F. Supp. 2d 1288, 1295 (M.D. Fla. 2007), in order to support a claim of causation. That is especially so here because, as defendants explained in their General Causation Brief, Hill acknowledged that the degree of evidence needed for biological plausibility would be higher where, as here, the

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73 (*See, e.g.*, Pls.' Br. at 29.)

74 (*Id.* at 8, 32-33.)

"knowledge of the day" has elucidated likely causal pathways – i.e., that cancer results from genetic cellular changes.[75]

In any event, plaintiffs distort Dr. Neel's testimony on this issue as well. Dr. Neel's testimony was not that proof of biological plausibility is always "'essential,'" as plaintiffs contend.[76] Rather, Dr. Neel testified that ***where***, ***as here, the*** "***epidemiological associations . . . are conflicting and weak***, the biological plausibility becomes essential."[77] In other words, biological plausibility is required with respect to perineal talc use and ovarian cancer specifically because other key factors – including strength of association and consistency of association – weigh against an inference of causation.[78]

This testimony is entirely consistent with the opinions of defendants' expert Dr. Christian Merlo. Plaintiffs assert that Dr. Neel's emphasis on biological plausibility is in tension with Dr. Merlo's conclusion that he did not need to assess

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[75] (Defs.' Mem. of Law in Supp. of Mot. to Exclude Pls.' Experts' General Causation Ops. at 79-80, May 7, 2019 (ECF No. 9736).)

[76] (Pls.' Br. at 32 (stating that "it is unsurprising that [Dr. Neel] feels that his area of study is 'essential' to determining the issue of causation").)

[77] (Neel Dep. 148:22-149:1).)

[78] Indeed, Dr. Neel specifically distinguished this situation, in which the associations between ovarian cancer and talc are weak and inconsistent, from the association between scrotal cancer and work as a chimney sweep, an example used by Hill in his speech, in which the association is so strong that it might plausibly support an inference of causation without a proven biological mechanism. (*See* Neel Dep. 148:13-20.)

biological plausibility in light of his analysis of other Bradford Hill considerations.[79] But these experts' opinions are merely two sides of the same coin. Dr. Merlo's point is not that evidence of biological plausibility is unnecessary for proving causation in general, but rather that causation cannot be proven where the evidence relating to strength and consistency of association and dose-response are so weak, essentially obviating the need to assess biological plausibility or the other Bradford Hill factors.[80] Dr. Neel's opinion is similar – that, where the evidence on other Bradford Hill factors is weak, only the strongest showing on biological plausibility could justify a continuation of the causation inquiry. Accordingly, plaintiffs' attacks on the reliability of Dr. Neel's opinions are baseless.

Second, plaintiffs' two challenges to the reliability of the opinions offered by Dr. Shih are similarly meritless. Plaintiffs initially argue that Dr. Shih "elevated the biological plausibility aspect of causation . . . into an absolute and singular requirement for an established molecular mechanism in order to show

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79 (Pls.' Br. at 8, 32.)

80 (Expert Report of Christian Merlo, M.D. M.P.H. at 30, Feb. 25, 2019 (attached as Ex. C13 to Tersigni Cert.) (citing Hill, *Environment and Disease: Association or Causation*, 59 Proc. Royal Soc'y Med. 296 (1965)); Dep. of Christian Merlo, M.D., M.P.H. 178:24-179:5, Apr. 18, 2019 (attached as Ex. B9 to Tersigni Cert.) ("[W]ith a lack of strength of association, with a lack of consistency between studies and with a lack of dose response, biologic plausibility doesn't matter because there's no causal association between talcum powder and ovarian cancer based on the medical literature.").)

causation," essentially rewording the argument they make against Dr. Neel on this score.[81] This argument fails for much the same reason. As already discussed, it is wholly proper to insist on strong evidence of biological plausibility in light of the weak to nonexistent evidence supportive of the other Bradford Hill factors and in light of the fact that science has established genetic mutations as the cause of cancer.

Moreover, plaintiffs mischaracterize Dr. Shih's testimony regarding the nature of the evidence required. Plaintiffs focus on Dr. Shih's testimony that "'you need to see a genetic mutation in order to establish [a] causal relationship,'"[82] as though to suggest that Dr. Shih was imposing a requirement of direct physical proof of such a mutation. But Dr. Shih was merely reciting the universally accepted notion that it is mutations that cause cancer and therefore a scientist asserting that an exposure can cause cancer must be able to show that it causes mutations. Dr. Shih was not saying – and indeed expressly disclaimed – that there is a need for "evidence of direct molecular pathology" to prove causation; instead,

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81 (Pls.' Br. at 38 (asserting that Dr. Shih – "like Dr. Neel – alters and elevate[s] the biological plausibility of causation (which is one aspect among many of Bradford Hill, not one of which is required)").)

82 (*Id*. (alteration in original) (quoting Shih Dep. 62:17-23).)

he testified that "cogent evidence and credible science [are needed] to support biological plausibility."[83] Thus, plaintiffs' argument on this score is a red herring.

Plaintiffs additionally contend that Dr. Shih's deposition testimony demonstrates that he followed a results-driven and unreliable methodology, citing testimony he gave in connection with his study.[84] But this argument again misconstrues Dr. Shih's words. As summarized above, Dr. Shih examined precursor lesions in fallopian tube tissue to ascertain whether inflammation was present and determined that there were no signs of inflammation in any of the slides involving precursor lesions rather than actual cancer. Dr. Shih concluded that these remarkably consistent findings support his opinion that inflammation does not play a role in causing ovarian cancer but instead might result from it.

At his deposition, Dr. Shih was asked whether he would conclude that inflammation could cause ovarian cancer if, in the course of "looking at more slides," he found some instances in which certain ovarian precursor lesions were associated with inflammation.[85] Dr. Shih thought this unlikely – not because he was wedded to the conclusion he had already drawn, but because, having found no inflammation in 48 slides, he believed that "the likelihood that we'll see chronic

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83 (Shih Dep. 63:23-64:2.)

84 (Pls.' Br. at 37-38.)

85 (Shih Dep. 111:21-112:2.)

inflammation in" a significant number of additional slides "would be very, very low."[86] Furthermore, and quite reasonably, Dr. Shih explained that since his opinion was based not only on his study but on the whole of the literature covering "epidemiology, chronic inflammation, carcinogenesis, molecular genetics" and on "20 years of experience as a scientist and pathologist," it would remain the same even if the results of his own study became somewhat less definitive.[87] Far from suggesting a results-oriented methodology or an opinion based on mere ipse dixit, Dr. Shih's response only serves to strengthen his opinion by demonstrating that it is rooted in far more than a single study.

For these reasons, too, plaintiffs' motion should be denied.

III. DR. BOYD'S BRIEF DISCUSSION OF MIGRATION IS ONLY PROVIDED AS BACKGROUND TO HIS OPINION ON DOSE AND IS IN ANY EVENT WELL WITHIN HIS EXPERTISE.

Plaintiffs also ask the Court to exclude Dr. Boyd's purported opinion regarding migration, i.e., whether perineally applied talc can reach the fallopian tubes or ovaries. According to plaintiffs, Dr. Boyd lacks the requisite expertise to address this issue.[88] This argument, too, lacks merit.

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86 (*Id.* 114:7-116:4.)

87 (*Id.* 112:3-14.)

88 (Pls.' Br. at 44-45.)

As an initial matter, Dr. Boyd does not actually offer an opinion regarding migration. Rather, in the following passage from his report, Dr. Boyd references IARC's statement that the evidence supporting plaintiffs' migration theory is "weak," as part of a broader discussion regarding Dr. Saed's failure to use a proper dose of talc in his experiment:

> **Determination of Talc Dosage:** Dr. Saed used a very highly concentrated talc solution – 500 mg of talc per 10 ml of DMSO. He then applied relatively enormous doses of talc – from 5 to 100 µg/ml – directly to the treated cells. This represents a far greater talc exposure than human ovarian cells would ever be subjected to under normal physiologic conditions – including as a result of regular perineal use of talcum powder. Indeed, the evidence that ***any*** talc can reach the ovaries from external perineal use is weak. Dr. Saed never estimated the amount of talc he believes would reach the ovary or the fallopian tubes as a result of perineal dusting, despite being directly asked, and other aspects of his deposition testimony support the conclusion that such an anatomical journey would prove improbable for talc particles. In attempting to explain why talc would not produce inflammation and cancer in the intervening areas of the female reproductive anatomy, for example, Dr. Saed repeatedly referred to the "wash" of bodily fluids that would expel particulate matter. Dr. Saed contrasted this protective mechanism to that of the ovaries, which he claims have no mechanism for removing foreign particles. But the logical conclusion of this argument would be that the same mechanisms of expulsion of talc from areas of the female reproductive tract distal to the ovaries (vagina, cervix, uterus, fallopian tubes) should also prevent talc from otherwise migrating – like a salmon upstream – through this wash of bodily fluids, eventually reaching the ovaries.
>
> Even accepting that talc could reach the ovaries to some extent, however, I am aware of no research suggesting that an amount approaching the quantities involved in Dr. Saed's study would ever reach the fallopian tubes or ovaries, and Dr. Saed appears to admit as much. As such, Dr. Saed failed to show that the dose range he used in his studies is applicable to human exposure levels and any subsequent

physiological sequela.[89]

The notion that Dr. Boyd, a prominent cancer researcher, is not qualified to cite IARC is a further example of plaintiffs' extreme double standard when it comes to qualifications. This is all the more true because, as the foregoing passage makes clear, Dr. Boyd only mentions the migration issue in order to underscore the unreliability of the dose of talc used by Dr. Saed in his talc experiments. As Dr. Boyd explains, Dr. Saed did not even attempt to calculate or use a realistic amount of talc in his research.[90] In addition, Dr. Saed contradicted himself with respect to dose by suggesting on the one hand that a woman's "body fluids" would "expel particulate matter," and assuming, on the other, that large amounts of talc take an "improbable journey" to women's ovaries or fallopian tubes when the product is applied perineally.[91] In other words, the gist of Dr. Boyd's opinion is that Dr. Saed's experiment used a wildly inappropriate amount of talc (an opinion plaintiffs notably do ***not*** challenge). Dr. Boyd was not offering a full-fledged opinion on

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89 (Boyd Rep. at 4-5 (footnotes omitted).)

90 As noted above, Dr. Boyd briefly suggests that he agrees with the International Agency for Research on Cancer that the evidence that talc can reach the ovaries after perineal dusting is weak and describes the reasons why it is unlikely that much (if any) talc can migrate from the external perineum to the ovaries. (*See id.* at 4-5 & n.10 (citing Int'l Agency for Research on Cancer, 93 *Monographs on the Evaluation of Carcinogenic Risks To Humans Carbon Black, Titanium Dioxide, and Talc* 411 (2010)).)

91 (Boyd Rep. at 5.)

whether (and if so, how much) talc can migrate to a woman's ovaries. *See Iconics, Inc. v. Massaro,* 266 F. Supp. 3d 461, 472, 475, 476 (D. Mass. 2017) (allowing expert to discuss background to frame opinions).

Needless to say, Dr. Boyd, an expert in the "molecular genetics of gynecologic . . . cancers," is clearly qualified to read an IARC report, to opine on the importance of dose in inducing carcinogenic mutations,[92] and to inform his opinion based on the relevant science. For this reason, too, plaintiffs' arguments should be rejected.

IV. DR. SHIH'S STUDY OF CHRONIC INFLAMMATION AND OVARIAN CANCER IS RELIABLE AND SHOULD BE ADMITTED.

Finally, plaintiffs seek to exclude Dr. Shih's histopathological study, which showed no inflammation associated with ovarian cancer precursor lesions, undermining plaintiffs' contention that inflammation can contribute to the development of HGSOC. Plaintiffs contend that the study is unreliable because: (1) "it is neither final nor complete"; (2) it ostensibly does not conform to the requirements of Rule 26 and, in particular, does not contain a discussion of its limitations or a written methodology; and (3) Dr. Shih did not take and produce "contemporaneous notes."[93] None of these contentions has merit.

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92 (Boyd Rep. at 1.)

93 (Pls.' Br. at 46-47.)

First, Dr. Shih's report is sufficiently final to satisfy the reliability requirements of *Daubert*. Whether a study, or even the techniques underlying it, has yet been published or subjected to peer review is relevant to the question of reliability, but is "not a *sine qua non* of admissibility." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993). In keeping with this principle, "it is acceptable . . . to rely on a study that is subject to future refinement and development." *Andrews v. Plains All Am. Pipeline, L.P.*, No. CV 15-4113 PSG (JEMx), 2018 WL 2717833, at *5 (C.D. Cal. Apr. 17, 2018).

Plaintiffs relatedly contend that a "hypothesis . . . cannot provide the foundation for an expert opinion,"[94] but while this is a correct statement of the law, it has no bearing here. As plaintiffs themselves explain, a "hypothesis is [just] an educated guess."[95] Here, by contrast, Dr. Shih's study offers complete findings supported by the underlying research, not a mere hypothesis. Dr. Shih ***began*** with a hypothesis, and framed a research question around that hypothesis. Then, in order to answer his question, and confirm or reject his hypothesis, he selected "59

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94 (Pls.' Br. at 46 (citing *Colon v. Abbott Labs.*, 397 F. Supp. 2d 405 (E.D.N.Y. 2005)).) Notably in *Colon*, the only case plaintiffs cite in support of their effort to exclude Dr. Shih's study, the court excluded reliance on an incomplete study, not so much because it was incomplete, but rather because the expert had not produced ***any*** reliable data in support of the conclusions that the expert put forward. 397 F. Supp. 2d at 410, 415.

95 (Pls.' Br. at 46.)

lesions and areas of interest" and examined them according to well-defined diagnostic criteria.[96] He reported his conclusions,[97] and offered an analysis and conclusions from his research results.[98] Even if it might be subject to further "refinement and development" before publication, *Andrews*, 2018 WL 2717833, at *5, the report stands as a full and complete evaluation of the cases that it identified and reviewed and thus suffices to support Dr. Shih's opinions.

Although plaintiffs seek to undermine this conclusion by plucking statements from Dr. Shih's deposition that supposedly suggest something different, none of those statements supports plaintiffs' contention that the study must run its course before it can support Dr. Shih's conclusions. For example, plaintiffs make much of Dr. Shih's statement that the study is "ongoing."[99] But Dr. Shih's statement was intended to ***contradict*** plaintiffs' assertion that his results were not final. Specifically, after plaintiffs' counsel mentioned "ongoing results," Dr. Shih interjected to clarify that the ***results presented were final***, but that the study of the topic was ongoing,[100] presumably in order to make it even more robust prior to

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96 (Shih Rep. at 25.)

97 (*See id.* at 26-27, 29.)

98 (*Id.* at 27-28.)

99 (Pls.' Br. at 49 (citing Shih Dep. 101:23).)

100 (Shih Dep. 101:18-24.)

publication.[101] Indeed, at his deposition, Dr. Shih consistently resisted plaintiffs' counsel's efforts to classify his results as preliminary. In another passage quoted in plaintiffs' brief, counsel suggested that the study as it exists was "not the full report," and Dr. Shih explained that it did, in fact, consist of "a full result" as of "this moment" but that it was "not a full report as a publication" – i.e., not in proper format to be submitted for publication.[102] In sum, there is nothing incomplete about the study results, and Dr. Shih did not suggest otherwise.

Second, plaintiffs contend that Dr. Shih's study lacks various elements that they claim are required for a Rule 26 expert report – in particular, an explanation of methodology and an acknowledgment of the study's limitations. But Dr. Shih's study report explains his methodology in detail, including how he designed his study, how he selected cases for review, and the criteria he used to identify inflammation in his samples.[103] Indeed, it is difficult to imagine what further explanation of methodology plaintiffs would require. Rather than grapple with the study's actual contents, plaintiffs instead point to Dr. Shih's testimony that to "wrap up [the] study," he would add "other ingredients, like [an] introduction,

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101 (*Id.* 109:11-110:2 (Dr. Shih noting his uncertainty whether the final version of the paper would publish only the results of this histopathological study or whether it might include other findings from other studies).)

102 (*Id.* 100:11-23 (quoted in Pls.' Br. at 48).)

103 (*See* Shih Rep. at 25-26.)

methodologies, result, [and] discussion."[104] But since Dr. Shih's study already substantively explains its methodology (and already reports results, and discusses them), the passage can only be read to mean that if and when Dr. Shih publishes his findings, he will organize them into the clearly delineated sections expected in published biology literature: introduction, methodology, results and discussion.

Plaintiffs' contention that Dr. Shih's study does not acknowledge its limitations is no more availing. As an initial matter, "limitations" are not a required portion of an expert report. Plaintiffs concoct this demand out of the Rule 26 requirement that an expert offer his or her entire opinion rather than "just the parts that are helpful to the proffering party."[105] But plaintiffs make no allegation that Dr. Shih hid any contradictory or unhelpful results in his study. Moreover, Dr. Shih's deposition obviously afforded plaintiffs ample opportunity to ascertain any limitations through deposition questioning – in fact, plaintiffs' counsel asked this question, and Dr. Shih expressly acknowledged that one limitation of the study was that an analysis of a greater number of slides would provide more information.[106] In any event, if Rule 26 did require an expert to include a formal discussion of limitations in an expert report, the same rule would require exclusion of plaintiffs'

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104 (Pls.' Br. at 48 (emphasis omitted) (quoting Shih Dep. 100:15-18).)

105 (*Id.* (citing Fed. R. Civ. P. 26(a)(2)).)

106 (Shih Dep. 110:15-111:16.)

experts' reports, including, most notably, the report of Dr. Saed, which includes rank speculation but provides absolutely no discussion of his study's limitations.[107]

Third, plaintiffs seek to exclude Dr. Shih's study because he allegedly did not take "contemporaneous notes."[108] But while taking contemporaneous notes is necessary in some contexts – e.g., to keep track of voluminous details and data – the need to take such notes is necessarily dictated by the nature of the work.[109] The guiding principle is the core requirement of *Daubert* and its progeny that an expert should "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *In re Paulsboro Derailment Cases*, 746 F. App'x 94, 98 (3d Cir. 2018) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Dr. Shih has done so here. As Dr. Shih explained, an experienced pathologist, whether in clinical practice or in preparation for litigation, does not "need to write down every single detail" when he is

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107 (*See generally* Saed Rep.)

108 (Pls.' Br. at 46.)

109 It is especially surprising that plaintiffs would invent a contemporaneous notes requirement in this litigation in light of the strong likelihood that one of their experts came up with so-called "contemporaneous notes" by fabricating them after the fact. (*See* Defs.' Mem. of Law in Supp. of Mot. to Exclude Expert Ops. of Ghassan Saed at 52, 54, May 7, 2019 (ECF No. 9736-2); Letter Op. from Hon. Joel A. Pisano to All Counsel of Record at 3, Apr. 26, 2019 (attached as Ex. G6 to Tersigni Cert.) (noting that Dr. Saed "was found to have altered laboratory notebook entries").)

reviewing slides, but rather needs only to write down "the final diagnosis."[110] This is all the more true because the diagnosis that Dr. Shih made was based exclusively on visual criteria, and the microscopic images he reviewed were all photographed to preserve the data underlying his conclusions.[111] Those photographs would allow another expert to evaluate and replicate Dr. Shih's work, and although plaintiffs presumably shared the photos with their own experts, plaintiffs have not suggested (at deposition or in their briefing) that Dr. Shih's evaluation of the slides was inaccurate.

In short, all of plaintiffs' objections to Dr. Shih's study misconstrue basic legal principles, or the nature of the study itself, or both. For this reason, too, plaintiffs' arguments should be rejected.

CONCLUSION

For the reasons set forth above, the Court should deny plaintiffs' motion exclude the opinions of defendants' experts Drs. Neel, Shih, Boyd and Birrer.

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110 (Shih Dep. 30:17-20.)

111 (*See* Shih Rep. at 26.)

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Respectfully submitted,

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